FEB 25 2005

BIONOSTICS
FERRARIS
Quality Solutions

510(k) Summary[1]

K050100

(a) (1) **Submitter's name, address**

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Contact Person

Kathleen Storro
Director, QA & Regulatory Affairs
(978) 772-7070 x 220

Date of preparation of this summary: 17 January 2005

(2) **Device trade or proprietary name:** RNA1c Hemoglobin A1c Control for Bayer DCA2000 and DCA2000+ Analyzers

Device common or usual name or classification name:

Glycosylated Hemoglobin Control

PRODUCT NOMENCLATURE	CLASSIFICATION NUMBER	CLASS	PANEL
Control, Single Analyte (Assayed or Unassayed)	862.1660 (JJX)	I	Chemistry

I. Substantial Equivalence

RNA1c Hemoglobin A1c Control for Bayer DCA2000 and DCA2000+ Analyzers is substantially equivalent in function, safety and efficacy to Bayer DCA 2000 Hemoglobin A1c Normal and Abnormal Control Kit. [K021484]

Comparison of Technological Characteristics with Predicate Device

Characteristic	New Device	Predicate Device
Name:	RNA1c Hemoglobin A1c Control for Bayer DCA 2000 and DCA2000 Analyzers	Bayer DCA 2000+ HbA1c Control
510(k), Date:		K021484, 06/14/2002
Description:	Red, aqueous solution with non-biological synthetic peptide	Lyophilized Hemoglobin Control
Intended Use:	As a quality control solution for use to verify the performance of the Bayer DCA 2000+ Analyzer for the measurement of HbA1c	As a quality control lysate to monitor the precision of laboratory procedures for measurement of HbA1c
Number of levels:	2	2
Analytes:	Glycated hemoglobin (HbA1c%)	Glycated hemoglobin (HbA1c%)
Container:	plastic bottle	3.5 mL clear borosilicate glass vial with plastic screw cap and phenolic moisture barrier liner.

[1] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Characteristic	New Device	Predicate Device
Serology Testing of Human Source Material	No serology testing is necessary. Non-biological solution with synthetic peptide	Non-reactive for: • Hepatitis B Surface Antigen • Antibody to Hepatitis C • Antibody to HIV-1 & HIV-2 • Syphilis (TPHA & RPR)
Storage:	2° - 8°C	2° - 8°C
Stability of Lyophilized Product:	N/A – liquid solution	3 years at 2° - 8°C
Stability in Liquid State (reconstituted)	12 months at 2° - 8°C	13 weeks at 2° - 8°C
Color:	Red	Dark red (after reconstitution)

II. Description of the new device

Glycosylated Hemoglobin (HbA1c) is a human hemoglobin A (HbA0) with glucose irreversibly bound to the N-terminal valine of the beta-chain. %HbA1c is the percentage of glycolsylated hemoglobin molecules as a percentage of the total hemoglobin concentration.

%HbA1c is quantified on medical devices by turbidimetric inhibition immunoassay (TINIA), ion-exchange HPLC, boronate affinity HPLC or gel electrophoresis.

The Bayer DCA 2000+ [K940971] determines HbA1c concentration by immunoassay and total hemoglobin concentration by colorimetry. Using the values obtained for each of these two analytes, the percentage of the total hemoglobin that is glycated is calculated and reported as HbA1c%.

RNA1c Hemoglobin A1c Control for Bayer DCA2000 and DCA2000+ Analyzers is a two-level, aqueous liquid control solution consisting of a synthetic peptide identical to the HbA1c epitope in a non-biological aqueous solution with dye to provide the appropriate total hemoglobin value. The concentration of dye and peptide are optimized for use on the Bayer DCA 2000 and DCA 2000+ Analyzers to provide measurement values for HbA1c equivalent to the predicate device, Bayer DCA 2000 Hemoglobin A1c Normal and Abnormal Control Kit.

RNA1c Hemoglobin A1c Control for Bayer DCA2000 and DCA2000+ Analyzers provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program. The product is packaged in a plastic bottle with dropper tip for application of the solution to the test cartridge.

RNA1c Hemoglobin A1c Control for Bayer DCA2000 and DCA2000+ Analyzers is a non-hazardous aqueous solution containing no biological materials and requires no reconstitution prior to use.

(5) Intended use of the device

RNA1c Hemoglobin A1c Control for Bayer DCA2000 and DCA2000+ Analyzers is intended to be used to monitor and evaluate the analytical performance of the Bayer DCA 2000 and DCA 2000+ Analyzers.

(6) Technological characteristics of the device.

RNA1c Hemoglobin A1c Control for Bayer DCA2000 and DCA2000+ Analyzers is a two-level, aqueous liquid control solution consisting of a synthetic peptide identical to the HbA1c epitope in a non-biological aqueous solution with dye to provide the appropriate total hemoglobin value. The concentration of dye and peptide are optimized for use on the Bayer DCA 2000 and DCA 2000+ Analyzer to provide measurement values for HbA1c equivalent to the predicate device, Bayer DCA 2000 Hemoglobin A1c Normal and Abnormal Control Kit.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Tests were conducted to verify specific performance requirements:

a) Closed bottle stability
b) Stability after opening
c) Correlation to predicate device
d) Test precision and range

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

N/A

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 25 2005

Ms. Kathleen Storro
Director, QA and Regulatory Affairs
Bionostics, Inc.
7 Jackson Road
Devens, MA 01432

Re: k050100
Trade/Device Name: RNA1c Hemoglobin A1c Control for Bayer DCA2000 and DCA2000+ Analyzers
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assay and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: January 17, 2005
Received: January 18, 2005

Dear Ms. Storro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050100

Device Name: RNA1c Control for Bayer DCA2000 and DCA2000+ Analyzers

Indications For Use:

RNA1c Control for Bayer DCA2000 and DCA2000+ Analyzers is intended to be used to monitor and evaluate the analytical performance of the Bayer DCA 2000 and DCA 2000+ Analyzers that measure HbA1c. The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practice. The two levels of controls allow performance monitoring within the clinically important range.

For *In Vitro* Diagnostic Use

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K050100